

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF LOUISIANA**

**IN RE: PROPULSID  
PRODUCTS LIABILITY LITIGATION**

**MDL NO. 1355**

**SECTION L**

**JUDGE FALLON  
MAG. JUDGE AFRICK**

**THIS DOCUMENT RELATES TO ALL CASES**

**PRETRIAL ORDER NO. 10**

**(Production and Preservation of Defendants' Electronic Data)**

The following protocol shall be followed for the format of production and preservation of electronic data of the defendants Johnson & Johnson and Janssen Pharmaceutica Inc.:

**A. Scope**

1. Except as specifically limited herein, the within procedures and protocols govern the production and preservation of discoverable electronic information (as defined below) by defendants and their domestic subsidiaries and affiliates (collectively, "defendants") during the pendency of this litigation.

2. Except as otherwise set forth herein, the within procedures and protocols apply solely to defendants' documents and data existing in electronic form (in the broadest sense consistent with Fed. R. Civ. P. 34(a)), including e-mail, electronic peer-to-peer messages, word processing documents, spreadsheets, electronic slide presentations, databases, and other electronic data items, now existing or hereafter created, containing information relating to facts at issue in the litigation ("discoverable electronic information").

### **B. Documents & Data to Be Produced**

#### 1. Electronic Files, Documents, & Databases

**Emails.** Electronic mail ("email") containing discoverable electronic information, together with the agreed meta-data associated with each such email, shall be produced in electronic form, in an accessible standard format, and on a standard media, in each case, as agreed to among the parties. Back-up and archival copies of email shall be maintained in accordance with section D, *infra*, pending negotiation of restoration procedures and protocols discussed in section C.2, *infra*. Defendants shall take steps intended to prevent any modifications, alterations, or additions to emails from their original state.

**"Office" documents.** Word processing files, computer presentations (*e.g.*, PowerPoint slides), stand alone databases (*e.g.*, Access), spreadsheets (*e.g.*, Excel) containing discoverable electronic information, together with the agreed meta-data associated with each such document, shall be produced in electronic form, in an accessible standard format, and on a standard media, in each case, as agreed to among the parties. Back-up and archival copies of documents (including final versions, related versions, and drafts) shall be maintained in accordance with section D, *infra*, pending negotiation of restoration

procedures and protocols discussed in section C.2, *infra*. Defendants shall take steps intended to prevent any modification, alteration, or addition as is necessary to create a comprehensive collection of such documents in their original state.

**Databases.** Databases containing discoverable electronic information and identified on attachment A, together with the agreed meta-data associated with each such database, shall be produced in a manner agreed to among the parties, subject to redaction of privileged or other non-discoverable information, either as used and maintained in the ordinary course of business (including any forms and variations thereof) or in such other form as may be agreed to among the parties. To the extent reasonably practicable, production shall include without limitation the software, manuals and computer readable code associated with any reports, file formats, forms, queries, or structure for any databases produced as used and maintained in the ordinary course of business. Back-up and archival copies of all databases containing discoverable information, regardless of whether identified in attachment A, shall be maintained in accordance with section D, *infra*, pending negotiation of restoration procedures and protocols discussed in section C.2, *infra*. Defendants shall take steps intended to prevent any modification, alteration, or deletion of the data in such databases but may continue to use such databases and add data to the extent that it does not cause data to be deleted. If plaintiffs subsequently discover additional databases not included on attachment A, they may request production of such consistent with the procedures outlined herein and Defendants shall not unreasonably refuse production.

**Research Materials.** All electronically stored research and/or reference literature and materials containing discoverable electronic information and identified on attachment B, together with the agreed

meta-data and indices associated with such materials, shall be produced in a manner agreed to among the parties, either as they are maintained in the ordinary course of business, whether electronically or in image form, as the case may be, but with appropriate redaction of privileged or other non-discoverable information), or in such other form as may be agreed to among the parties. If plaintiffs subsequently discover additional reference literature and materials not included on attachment B, they may request production of such consistent with the procedures outlined herein and Defendants shall not unreasonably refuse production.

**Other.** To the extent any other documents containing discoverable electronic information are identified, the parties shall meet and confer to determine the manner of production of such documents and any agreed meta-data associated therewith. Defendants shall not unreasonably refuse production of such documents. Back-up and archival copies of such other documents (including final versions, related versions, and drafts) shall be maintained in accordance with section D, *infra*, pending negotiation of restoration procedures and protocols discussed in section C.2, *infra*. Defendants shall take steps intended to prevent any modification, alteration, or addition as is necessary to create a comprehensive collection of such documents in their original state.

**Software.** Software and operating manuals shall be produced by defendants to enable plaintiffs to access and view any discoverable electronic information produced pursuant to this Pretrial Order. Software shall mean proprietary software or any other software not commercially available for purchase at retail stores in the United States (e.g. Microsoft Office Suite or Corel Office Solutions). A reasonable number of copies of such software and operating manuals shall be made available for use by the parties

receiving the discovery during the pendency of the litigation. Plaintiffs shall not use software produced by defendants for any purpose, commercial or otherwise, other than the prosecution of this litigation. During the pendency of the litigation, any software produced by defendants shall be treated as confidential information in accordance with Pretrial Order No. 5. At the conclusion of the litigation, such software shall be returned to defendants.

2. System-Level Meta-data

The parties are to continue meet and confer discussions to identify any system-level meta-data to be produced beyond that already provided by defendants. Such data may include back-up and archival data, computer system data and computer access data.

3. Redaction Software

Defendants shall describe to plaintiffs the procedures and software used to redact any documents or data existing in electronic form such that plaintiffs can identify how information was redacted and can obtain and or evaluate the software.

**C. Identification of Responsive Electronic Data**

1. All email and electronic data (excluding databases) manually identified or segregated by defendants' employees, agents, contractors, or consultants as containing discoverable electronic information, as well as all electronic data existing within directories reasonably identified as being related to Cisapride, shall be timely reviewed in their entirety by defendants for responsiveness and privilege, and thereafter such discoverable electronic information which is neither privileged nor otherwise protected shall be produced electronically in accordance with the guidelines herein. The parties shall meet and confer to

establish a timetable for the production of such data. Should the parties be unable to agree on a reasonable timetable for production, the court shall resolve such disputes.

2. By April 26, 2001, defendants shall produce a catalog or index of all back-up and archival copies of electronic data that is specified in section A.2, *supra*, “Back-up and archival data.” The parties shall meet and in good faith confer to identify those tapes likely to create a reasonably comprehensive representation of the discoverable electronic information contained on all archival and back-up media of defendants and determine to what extent back up and archival tapes may be restored. In selecting any back-up and archival tapes for restoration, the parties shall endeavor to avoid the unnecessary restoration of duplicate or non-responsive data.

3. To minimize the burden associated with searching all electronic data collected other than such data collected and reviewed in accordance with paragraph C.1 above, including any data restored in accordance with the procedures herein (excluding databases), such data will be pre-screened for responsiveness utilizing search terms agreed upon by the parties. The parties shall cooperate to identify query terms designed to retrieve discoverable electronic data. Documents responsive to any agreed query search shall then be reviewed by defendants for responsiveness and privilege, and thereafter produced electronically in accordance with the guidelines herein. Defendants shall reasonably accommodate plaintiffs’ requests for (i) searches of newly created data, and (ii) modified searches on previously searched data.

4. Defendants’ search and review shall be conducted in a manner designed to preserve all meta-data (such as file creation and modification dates) associated with the discoverable electronic information being searched or reviewed. The parties shall jointly develop search and review procedures

designed to preserve, without alteration or modification, all meta-data associated with defendants' discoverable electronic information.

#### **D. Preservation of Electronic Data**

1. During the pendency of this litigation, defendants shall maintain electronic document and data retention policies designed to ensure the retention of defendants' discoverable electronic information. In connection therewith, defendants shall (i) maintain back-up procedures designed to back up all network storage devices potentially containing discoverable electronic information; (ii) suspend the routine or automatic deletion of discoverable electronic information, including the automatic deletion of electronic mail or removal of unused electronic data and files; and (iii) secure the hard drives (or mirror image back-ups of such hard drives) of all computers (including laptop or desktop computers used by defendants' employees and/or contractors (as defined in paragraph 5 below)) potentially containing discoverable electronic information that are not backed up in the ordinary course, before the reformatting, redeployment, or disposal of such hard drives. With respect to items (ii) and (iii), *supra*, these steps shall be interim measures followed while the parties develop agreed alternative measures to accomplish the preservation of data subject to the procedures in items (ii) and (iii).

2. All electronic information or data archived or backed up as part of a special back-up, whether due to system upgrade, transition planning, system migration, disaster recovery planning, Y2K testing, or any other reason, that potentially contains discoverable electronic information shall be securely retained for the remainder of the litigation.

3. All current or legacy software and hardware necessary to access, manipulate, print, etc., discoverable electronic information that is either “live” or has been archived or backed up shall be securely retained for the remainder of the litigation. If necessary, the parties shall meet and confer to develop procedures designed to minimize any undue hardship associated with the continued retention of such items.

4. Any existing or hereafter created “full” (as opposed to incremental) back-up tape or other back-up storage media (collectively, “back up tape”) created on a monthly basis, as well as any full back-up tape created on a periodic basis greater than a month (*e.g.*, quarterly or yearly back-up tapes) that potentially contains discoverable electronic information shall be securely retained until December 31, 2002. No later than December 1, 2002, the parties shall meet and confer concerning the disposition of back-up tapes and present to the Court no later than December 15, 2002, the parties’ joint (or if not joint, competing) proposals for the continued treatment of such back-up tapes.

5. Defendants shall obtain certifications on behalf of all employees or independent contractors who (1) work at defendants’ facilities for a duration longer than two weeks and (2) are reasonably believed to create, alter or access discoverable electronic information on their non-network storage devices (i.e., desktop hard drives, laptop hard drives, and home computer hard drives), that such devices and any back-up tapes thereof maintained by each such employee or contractor have been searched for discoverable electronic information and any such data has been copied to a backed-up network storage device for the preservation of the same. Defendants shall instruct such employees and contractors in the manner of copying such files so as to retain, without modification or alteration, all meta-data (file creation dates, modification dates, etc.) associated with the files at issue. Defendants shall on a semiannual basis have such employees and contractors that potentially possess discoverable electronic information certify that any



newly created data has been copied to a secure, backed-up network storage device to ensure its preservation. The parties shall meet and confer to develop the form of notice and certification directed to defendants' employees, as well as the procedures to be used by defendants' employees and contractors when searching for and copying discoverable electronic information.

6. Defendants shall implement specific steps to monitor their employees' compliance with the preservation guidelines herein. To that end, the parties shall meet and confer to develop specific procedures to effectuate such monitoring. Further, defendants shall conduct random audits of their employees' non-networked storage devices following receipt of the semiannual certifications required under paragraph D.5 herein. In connection with each semiannual audit, defendants shall search the non-networked storage devices of not less than 10 of their employees believed to possess discoverable electronic information to determine if any discoverable electronic information, not otherwise stored on a network storage device, exists on those employees' non-networked storage devices. Defendants shall, on a regular basis, report to plaintiffs the results of such audits and, if requested, provide to plaintiffs certifications from those employees whose devices were audited. The parties shall meet and confer to implement any additional procedures needed to ensure the effective preservation of discoverable electronic information contained on non-networked storage devices. In the event the parties, after meeting and conferring, are unable to agree that monitoring or effective preservation have been accomplished the parties shall submit their dispute to the Special Master. Defendants shall maintain records of any compliance audit undertaken in accordance with this paragraph. The reports of any compliance audit by defendants shall be securely retained by defendants in the event that such information may need to be submitted to the Court or Special Master.

7. Consistent with the Court's statements during the February 20, 2001 and March 15, 2001 status conferences, defendants shall take specific measures to preserve discoverable electronic information possessed by their international subsidiaries and affiliates. To that end, defendants shall use their best efforts to implement the preservation procedures and protocols contained herein to preserve discoverable electronic information possessed by such entities. Defendants shall timely notify plaintiff's counsel of any instances where implementation is not reasonably practical. Defendants will meet and confer with plaintiffs further to the extent that the implementation of the preservation procedures and protocols contained herein by their international subsidiaries and affiliates is impracticable in light of the systems utilized by such entities and to develop acceptable procedures and protocols for such entities designed to achieve the preservation of discoverable electronic information possessed by them.

8. Except as to those matters and procedures provided herein, defendants' preservation obligations with respect to electronic data pursuant to Pretrial Order No. 2, VIII(B) shall remain in full force and effect.

#### **E. General Instructions**

1. Each individual piece of computer media produced must be clearly labeled with a unique media control or "Bates" number that is indelibly written on, or affixed to, both the media itself and any enclosure or case produced with the media. This label or marking shall be affixed in a place and manner that does not obliterate any labeling on the original media, and that does not interfere with the ability to examine or use the media.

2. Electronic records and computerized information must be produced with sufficient information to permit identification of the producing agent and business unit responsible for the production.

This information shall include, without limitation:

- a) The name of the corporation or other entity who is producing the information, along with information such as country, city, site, and department sufficient to uniquely identify the producing agent;
- b) The name or identity of the specific server or computer system from which the back-up was produced or information copied;
- c) To the extent reasonably known, the name or identity of the specific server or computer system upon which the information was originally created; and
- d) To the extent reasonably known, the name or identity of the specific server or computer system upon which the information was maintained during the course of normal business, if different from the system where it was created.

The parties shall meet and confer to develop a standard form containing the information required pursuant to this paragraph.

3. Electronic records and computerized information must be produced in an intelligible format or together with a technical description of the system from which they were derived sufficient to permit rendering the records and information intelligible. To the extent necessary to enable plaintiffs to render the records and information intelligible, this description shall include:

- a) The manufacturer's name and model number for electronic hardware used to create and maintain the electronic records;
- b) The name and version of the operating system used on the computer where the electronic records were created and maintained;
- c) The manufacturer's name, product identification, and version number for any software used to create and maintain the electronic records, along with any proprietary software, written documentation, special parameters, and instructions sufficient to permit those records to be read from the media produced; and
- d) The date, if known, when the information was first created, along with the date of its most recent modification.

4. To the extent that decryption or access passwords are necessary to unlock any computerized information in its original form, including without limitation electronic mail passwords and file decryption passwords, the parties shall meet and confer to develop appropriate steps to allow plaintiffs to access the data without compromising defendants' confidentiality, security, or proprietary interests.

5. Except for non-responsive, privileged, or otherwise protected information, any record, document, or data item that was created on a computer or computer system and is to be produced pursuant to this protocol must be produced without redaction, on some form of computer media. For all such media produced, external labels on the media shall identify the computer(s) from which the copies of computer files were made, and the full names of the individuals or business units who used the computer so identified. A record shall also be maintained and produced showing how the information on the media was copied.

6. Should the producing party seek to withhold any document based on some limitation of discovery (including but not limited to a claim of privilege), the producing party shall supply a list of the documents for which such limitation of discovery is claimed, indicating:

- a. The identity of each document's author, writer, sender;
- b. The identity of each document's recipient, addressee, or person for whom it was intended;
- c. The date of creation or transmittal indicated on each document, or an estimate of that date, indicated as such, if no date appears on the document or in meta-data information;
- d. The general subject matter as described on each document, or, if no such

description appears, then some other description sufficient to identify the document; and

- e. The claimed grounds for the limitation of discovery (*e.g.*, “attorney-client privilege.”).

7. Should the producing party seek to redact any document based on some limitation of discovery (including but not limited to a claim of privilege), the producing party shall supply a list of the documents for which such limitation of discovery is claimed, indicating:

- a. The claimed grounds for the redaction;
- b. The nature of the redacted material (*e.g.*, “patient name,” “trade secret,” etc.); and
- c. A description of the exact process used for redaction.

During the pendency of the litigation, an electronic copy of the original unredacted data shall be securely preserved in such manner so as to preserve without modification, alteration, or addition the content of such data, including any meta-data associated therewith.

8. All computer media must be properly packaged to ensure safe shipping and handling. If any piece of media produced is known to have any physical defect, electronic defect, or damaged data, or is infected with any virus or other harmful software of any kind, it should be clearly labeled so that appropriate care can be taken during its examination.

9. All computer media that is capable of write protection should be write protected before production.

10. All copies of computer files for production shall be created in such a way as to preserve or record the original directory structure and system-level meta-data (file name and path, create, modify, and access date and time, and size).

11. Following the production of electronic data, defendants shall cooperate and provide reasonable assistance to plaintiffs in connection with the installation and use of such data and software.

12. Where documents or electronic data requested herein are not available in electronic form, such documents or data shall be produced in accordance with Pre-Trial Order No. 8.

13. All data or documents to be produced hereunder shall be produced in English, if available.

14. The parties shall meet and confer to develop appropriate provisions for authenticating electronic data or documents produced herewith, and for using such at deposition or in any other evidentiary manner.

15. The parties shall meet and confer to develop appropriate provisions for the distribution of and access to electronic data or documents produced herewith. Until a protocol is developed, plaintiffs shall not disseminate or provide access to the electronic data or documents produced herewith to anyone other than a partner, member, associate, employee, or consultant associated with or retained by a firm that is a member of the Plaintiffs' Steering Committee in this litigation, or of any other committee or subcommittee of Plaintiffs' Steering Committee in this litigation..

## **F. Cost Allocation**

The procedures and protocols herein pertaining to restoration of back up and archival data and production of electronic information are subject to the development of reasonable and appropriate cost allocation agreements to provide for the apportionment of costs amongst the parties.

#### **G. Timing & Sequencing of Electronic Discovery**

1. Defendants shall commence the production of discoverable electronic information by May 1, 2001.
2. Defendants shall make best efforts to sequence the production of discoverable electronic information consistent with plaintiffs' requests concerning such discoverable electronic information.

#### **H. Resolution of Disputes Concerning Electronic Discovery**

- 1 The court shall appoint a Special Master concerning disputes relating to the scope and production of discoverable electronic information.
2. Where the parties are unable to resolve any issues concerning the scope and production of discoverable electronic information through the meet and confer conferences required by this Order, the parties shall, in the first instance, attempt to mediate their disputes with the Special Master. In the event that the parties are unable to resolve their disputes through mediation, the Special Master shall provide the Court with a recommendation for the resolution of the same.
3. By no later than April 26, the parties shall present the Court with a proposed order providing the details of the Special Master appointment. By that date, the parties shall also present an agreed candidate for appointment of a Special Master or, if agreement cannot be reached, each side will



present no more than two candidates with a brief statement as to the respective position of the parties on the candidates.

**I. Other Production and Preservation Electronic Data Orders**

Should any other court order or the defendants enter into any agreement regarding the production and preservation of Defendants' Electronic Data that provides any greater advantages or provides for the production or preservation of electronic data in a form or substance more advantageous than those provided by the present Pre-Trial Order, those same advantages or terms shall be extended to the plaintiffs in this litigation.

New Orleans, Louisiana, this 19 day of April, 2001

/s/ Eldon E. Fallon  
UNITED STATES DISTRICT JUDGE